GE Medical Systems

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General Electric Company
W-711
P.O. Box 414
Milwaukee, WI 53201

8 December 2000

Dockets Management Branch
Room 1061, HFA-305
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 00D-1497

We wish to submit comments on material presented in *Compliance Guidance: The Mammography Quality Standards Act Final Regulations, Document #4.*

Regarding 21 CFR 900.12(b)(8)(i)(B), Application of compression, Fine adjustment compression control

We appreciate FDA's efforts to clarify the status of the compression control on Senographe™ 500T and 600T systems with respect to this rule. We agree with FDA's recommendation that a facility should assess the state of compliance of a unit with all rules before considering a modification of a system based on this particular rule. However, GE Medical Systems does not intend to offer a modification of the compression control for these systems. Hence, we would greatly appreciate your deleting the sentence, "Facilities wishing to modify their units may contact their GE service representative for more information."

Regarding 21 CFR 900.12(b)(10) and (e)(5)(i), Automatic Exposure Control

It is stated in these sections that after October 28, 2002, technique charts may only be used outside the thickness range of 2 to 6 cm. However, the test of automatic exposure control performance is to be done "over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility." It would seem that the appropriate place to document the kVp range used clinically in the facility is in the technique chart. Additionally, FDA advises that manual exposure control mode can be used with a technique chart in the event of failure of the AEC. Presumably, this operating mode is not restricted to thicknesses outside the 2 to 6 cm range.

It would be helpful if FDA would clarify the role of the technique chart after October 28, 2002. It seems that it would not serve the quality of mammography to have one that is blank for thicknesses in the 2 to 6 cm range. Values of kVp are needed for AEC performance evaluation, for those AEC modes in which kVp is not automatically selected, and for use in case of AEC failure. Rather than eliminating the technique chart, it seems the intent of the rule is that density control settings cannot be used clinically in the 2 to 6 cm range after October 28, 2002. If FDA agrees with this interpretation, perhaps it could

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provide guidance indicating that the technique chart will continue to play an important if somewhat more limited role in the future. In fact, obtaining density consistency at the level of ± 0.15 OD for thicknesses less than 2 cm and greater than 6 cm may require more attention to the use of a technique chart than is currently the custom.

Regarding 21 CFR 900.12(b)(10) and demonstrating compliance of AEC performance

In discussing the methods to demonstrate compliance with the requirement, frequent reference is made to the "contact configuration." We do not believe that this term is defined either in the regulation or in guidance. One might infer that the breast is in close proximity to the image receptor in contrast to a magnification configuration. But in this geometry, mammography can be performed either with or without the grid and with either the large or small focal spot. For some systems, it can be done with various SIDs. What range of equipment parameter selections is intended by FDA's use of the term "contact configuration"?

For the third method of demonstrating compliance with the rule, could FDA please clarify what is meant by maintaining "the mean film optical density within ± 0.30 OD…in all configurations used clinically by the facility"? Is a single mean optical density calculated using the data from all configurations and individual values from each configuration compared to this grand mean?

Is a mean optical density calculated for each configuration and values for a particular configuration compared only to the mean for that configuration? The last sentence of the method, "The action limit applies only within each specific configuration tested and does not apply to data collected across the different configurations," would suggest that this might be the correct interpretation.

Is the mean optical density for each configuration to be within ± 0.30 OD (± 0.15 OD after October 28, 2002) of the mean optical density of every other configuration? That is, if a facility chose to perform magnification images at 1.5 ± 0.15 OD and screening images at 1.9 ± 0.15 OD, would it be out of compliance with the 2002 requirement?

Perhaps it would be clearer to state, "for each configuration, over the 2 to 6 cm thickness range the density of any film must be within ± 0.30 OD (± 0.15 OD after October 28, 2002) of the mean optical density of that configuration."

Regarding 21 CFR 900.12(c)(4) and the impact of FFDM

We recall that the issue of non-film image distribution was raised by Dr. Robert Nishikawa at the last NMQAAC meeting and we agree with his suggestions. This guidance should be modified to state that the mammogram must be provided in a form that is useful to the recipient. Even now some facilities have the capability of exchanging digital images and can do so much more expeditiously than mailing a hard copy film. When images can be transmitted virtually instantaneously via telemammography and over networks, why impose a restriction that only serves to delay the delivery of healthcare? For the untrained layperson, a film mammogram is nearly as inscrutable as a CD-ROM. However, if that person is transporting her image from one FFDM-equipped facility to another, the image on the CD-ROM is likely to contribute far more to the quality of mammography than a hard copy image.

Regarding Table: Required QC Tests for Facilities Using Multiple Units & Screen-Film Combinations

We recommend that the test of "AEC Performance – kVp & Thickness Tracking" should, in general, be performed for all S-F combinations for which the unit was calibrated. In this test the ability of the AEC detector to compensate for the shifts in energy spectral content of the x-ray beam due to kVp and object thickness is being evaluated. If the various screens differ only in their transmission of optical radiation to the film, the effects on the x-ray spectrum are probably negligible. But if the screens differ in phosphor composition or thickness or both, the spectrum seen by the AEC detector will change even if the kVp and object thickness remain the same. Hence, unless the physicist has knowledge of the manner of differences among the screens, it would be best to test all S-F combinations. Of course, the physicist must also remember to select the AEC calibration selection appropriate to the S-F combination.

Thank you for your consideration of these comments.

Sincerely,

John M. Sandrik, Ph.D.
Imaging Physicist

John M. Sandrik, W-711

GE Medical Systems

General Elcctric Company
P.O. Box 414, Milwaukee, WI 53201
gemedicalsystems.com

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